

REMARKS

Reconsideration of the above-identified application in view of the aforementioned amendments and following arguments is respectfully requested.

Claims 1-2, 9, 15, 27, 39 and 46-49, 73-74, 76 and 78 have been amended. No new matter has been added as a result of these amendments. Claims 81-86 have been added and no new matter has been added as a result of the addition of these claims.

Claim 48 is objected to under 37 C.F.R. Section 1.121(c) as being in improper amended format. Specifically, the Examiner states that Applicants amended this claim to replace "39" in line 3 with ---47--- while not using the correct amendment format. Applicants have reviewed this claim and agree with the Examiner's assessment. Applicants kindly thank the Examiner for pointing out this mistake. Claim 48 has been amended using the correct amendment format.

Claims 73 and 78 are objected to for containing errors. Specifically, claims 73 and 78 refer to molecular markers "umc1117" and "bnlg" that are found in Figure 1. As the Examiner points out in the Office Action, it appears that Applicants intended to recite the molecular markers umc1117 and bnlg490. Applicants thank the Examiner for pointing out this typographical error. Claims 73 and 78 have been amended to refer to the molecular markers "umc1117" and "bnlg490".

Claims 1-2, 9, 15, 27, 39, 46-47, 49, 73 and 76 and the claims dependent thereon, are rejected because of the phrase "*Tcb* gene cluster". Specifically, the Examiner states that this phrase is "new matter". While Applicants disagree with this rejection, in order to advance prosecution, these claims have been amended to recite "gene cluster". Support for this amendment to the claims can be found on page 15, line 10.

Claims 9-17, 21-26, 39-50 and 59-68 remain, and new claims 73-80, are rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner states that the location of the *Tcb* gene cluster and the *Tcb* locus have only been determined for plants in which the gene cluster and loci were derived from W22-TCB, which is the result of the cross of a particular *Zea mays* plant and a particular teosinte accession, each of a particular genotype. The Examiner also says that “[T]he confusion in the specification as to the actual composition of the *Tcb* gene cluster, including the presence or absence of the modifier gene and other genes, as discussed previously and below; reinforces the Examiner’s position that no guidance has been provided regarding any conserved sequences which are correlated with *Tcb* gene cluster function or *Tcb* locus function, which are conserved throughout the broadly claimed genus of any *Tcb* locus, any *Tcb* gene cluster, any ‘modifier’ gene, any ‘pollen effect’ gene, any ‘silk effect’ gene from any plant resulting from the cross of any two parents.”

With respect to the modifier gene, the Examiner states that “only *anecdotal* reference to the supposed location of one modifier gene is provided and that the genus is stated to encompass any modifier gene on any chromosome. No molecular markers have been described which would be useful for isolating any of the putative modifier genes.” The Examiner also goes on to state that an “assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product”. Applicants respectfully traverse this rejection.

As stated in the previous Amendment, the inquiry into whether the description requirement is met is determined on a case-by-case basis and is a question of fact. Section 2163 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). When a question regarding the adequacy of the

written description arises, the fundamental factual inquiry is whether the specification conveys to those skilled in the art, as of the filing date sought, that Applicant was in possession of the invention being claimed. Section 2163.02 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003).

Possession can be shown in a number of ways. For example, an Applicant can show possession by: (1) an actual reduction to practice of the claimed invention; (2) a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention; or (3) any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Id.*

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. Section 2163.04 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. *Id.* The Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicants disclosure a description of the invention as defined by the claims. *Id.* "A general allegation of unpredictability in the art is not a sufficient reason to support a rejection for lack of adequate written description." *Id.* The *Manual of Patent Examining Procedure* even cautions Examiners that "rejection of an original claim for lack of written description should be rare." (See Section 2163 *Manual of Patent Examining Procedure* (8th Edition, Rev. 1, Feb. 2003)).

Contrary to the arguments made in the Office Action, Applicants submit that the specification adequately describes the claimed invention. Specifically, in describing the TCB trait of the present invention, Applicants have provided information of the location of the gene cluster responsible for this trait (the short

arm of chromosome 4 between map units 40-85 as shown in Figure 1) and that this gene cluster is expressed dominantly (See page 15 of the specification). Applicants have also described the location of the *Tcb* locus (See page 15 of the specification, lines 16-20). Applicants have also described the approximate location of the modifier gene (See page 16 of the specification, lines 23-26). Applicants have also provided the molecular markers that can be used to identify the gene cluster associated with the TCB trait (See page 18 of the specification, lines 14-30). The use of these markers in conjunction with deposited dent inbred W22-TCB allows those of ordinary skill in the art to use routine, well-known techniques to identify other maize plants that contain the TCB trait.

In view of this detailed description provided in the specification, Applicants respectfully submit that the Office Action fails to provide sufficient factual evidence to rebut the presumption that the description as filed is inadequate. Moreover, the Office Action fails to present any factual evidence as to why a person of ordinary skill in the art would not recognize in Applicants disclosure a description of the invention as defined by the claims. Therefore, in view of the absence of such evidence, Applicants submit that this rejection should be withdrawn.

Claims 9-17, 21-26, 39-50 and 59-68 remain, and new claims 73-80 are rejected under 35 U.S.C. Section 112, first paragraph, as being enabled for claims limited to maize plants containing the TCB trait from maize line W22-TCB (ATCC No. PTA-1601) and methods of using these plants. The Examiner states that the specification does not reasonably provide enablement for claims broadly drawn to any maize plant containing any TCB trait or gene cluster, any *Tcb* locus, any "modifier gene", any "pollen effect" gene, any "silk effect" gene, or methods of using them. The Examiner maintains that it is unclear what the *Tcb* locus and *Tcb* gene cluster comprise, even in the exemplified W22-TCB. Specifically, the Examiner says that page 7 of the specification indicates that the *Tcb* gene cluster may or may not contain a modifier gene. The Examiner further refers to page 16,

lines 23-24 of the specification that indicates that the Tcb gene cluster “can also contain at least one modifier gene”. According to the Examiner, it is unclear whether or not the Tcb gene cluster actually contains one or more modifier genes, given the contradictory statements in the specification. The Examiner argues that in view of such contradiction that one skilled in the art would not have been able to utilize any molecular marker putatively associated with a modifier gene which may or may not comprise the claimed invention. Moreover, the Examiner goes on to state that “...molecular markers which are clearly associated with even one modifier gene, let alone non-exemplified modifier genes on different loci within chromosome 4 or on different chromosomes, have not been disclosed. Even had they been disclosed, the mere provision of an assay (i.e. molecular markers and proposed methods for their use) is insufficient to provide one skilled in the art with the actual product (namely corn plants which contain the Tcb locus or Tcb gene cluster which were obtained by crossing a multitude of non-exemplified parents).”

Additionally, the Examiner goes on to maintain that Goldman et al. clearly demonstrates that the choice of parents greatly influences the location of molecular markers on particular chromosomes. The Examiner argues that Applicants have not provided any molecular marker data for any plants that allegedly contain the Tcb locus or Tcb gene cluster, where said Tcb locus or Tcb gene cluster was obtained by crossing two parents other than the parents other than the parents of W22-TCB. Applicants respectfully traverse this rejection.

As discussed in the last Amendment, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent application coupled with information known in the art without undue experimentation (*Manual of Patent Examining Procedure*, 8th Edition, August 2001). As discussed in their previous Amendment, Applicants have described in their specification how the TCB trait comprises a TCB gene cluster that is expressed dominantly and located on the short arm of

chromosome 4, between map units 40-85 (See Figure 1). The TCB gene cluster further includes a *Tcb* locus. Moreover, as described in the specification on page 18, lines 14-20, a number of molecular markers, including those between phi021 and nc005 shown in Fig. 1 and the markers including and between umc 1117 and bnlg 490 shown in Fig. 3B can be used to identify the *Tcb* locus. Additionally, as further described in the specification on page 15, lines 19-20, the *Tcb* locus is located at about 6 map units (or centiMorgans) distal to the *sugary1* marker on chromosome 4S, about 40 map units (or centiMorgans) from the *Ga1* marker. The *Tcb* locus contains genes responsible for the silk effect function and pollen effect function. The characteristics of the gene(s) that encode the “silk effect” and “pollen effect” are described in detail on page 15, lines 21 – page 16, lines 9-15.

With respect to the “modifier genes”, the specification on page 16, lines 23-30 and page 17, line 1, describes the modifier genes and how such genes can be located. In fact, the specification on page 16, lines 25-26 describes at least one modifier gene that modifies the effect of the *Tcb* locus and is located near the *Tcb* locus in the direction of the *Ga1* marker (see Fig. 1).

Applicants submit that plants grown from the seeds of inbred line W22-TCB along with the description on pages 15 and 16 of the specification, as well as the molecular markers described on page 18 of the specification can all be used in combination by those skilled in the art to identify other plants that exhibit TCB traits, *Tcb* gene clusters, *Tcb* loci and modifier genes using routine experimentation in the art.

The Examiner simply has not provided any evidence other than his opinion that one reasonably skilled in the art could not make or use the presently claimed invention based upon the specification as filed without undue experimentation. Thereupon, in view of the aforementioned arguments, Applicants submit that this rejection should be withdrawn.

Claims 1-5, 9-17, 21-35, 39-50, 55-66 and 69-72 remain, and new claims 74, 77 and 79 are rejected under 35 U.S.C. Section 102(b) as being anticipated by Kermicle et al. (1990). Specifically, the Examiner states that Applicants argument that the Tcb locus or Tcb gene cluster do not contain the TIC-CP1 gene taught by Kermicle et al. (1990) (and as also set forth in the Kermicle declaration of 15 April 2004), contradicts other statements contained in the specification. In support of his argument, the Examiner refers to page 16 of the specification that states that the Tcb locus comprises gene(s) encoding a "pollen effect" (lines 9-10). The Examiner also refers to page 17 of the specification, lines 6-7 that states that the "TIC-CP1 gene(s) is associated with the pollen effect function of Tcb". The Examiner says that these statements contradict the assertion that the Tcb locus does not contain TIC-CP1. Additionally, on page 8 of the Office Action, the Examiner states that, "...page 17 of the specification teaches that W22-TCB contains the 'gene cluster described herein', including 'the Tcb locus and at least one gene(s) which encode for the silk and pollen effect functions and at least one modifier gene', and 'W22-TCB also contains TIC-CP1' (see lines 17-22). Thus, page 17 of the specification indicates that a plant that contains the Tcb locus also contains the TIC-CP1 gene." Furthermore, the Examiner notes that Kermicle et al. (1990) teach the presence of "TIC-CP2 in their plants (see, e.g., page 405, Figure 3 and page 406, Figure 4), while Figure 4B of the instant specification also teaches the presence of this gene in the instant gene cluster conferring the TCB trait."

Finally, the Examiner argues on page 9 of the Office Action that "...no evidence has been provided that Kermicle et al. (1990) did not disclose a plant with the same genetic complement as W22-TCB. The further characterization of the prior art plant with respect to the presence of molecular markers or modifier genes does not confer patentable distinction to the plant itself, which was characterized by Kermicle et al. (1990) as containing 'additional factors', and which is characterized in the instant specification as indeed containing TIC-CP1. Furthermore, Kermicle et al. (1990) do teach the analysis of DNA for the presence of the CP2 gene in relation to other chromosomal loci including su1, Ts5, Ga1 and the centromere (see page

405, Figure 3).” Applicants respectfully traverse this rejection.

Applicants respectfully submit that the maize plants taught by Kermicle et al. (1990) are not the same as the maize plants of the present invention. A summary of the differences between the claimed invention and Kermicle et al. (1990) are provided below in Table A.

TABLE A

	Maize plants that contain a gene cluster that encodes the teosinte crossing barrier (TCB) trait (Plants of the Present Invention)	Maize plants that contain genes that encode the TIC trait described by Kermicle et al. (1990).
Is the TIC-CP1 phenotype a component of the cross-incompatibility barrier?	NO - NOT A COMPONENT OF THE TCB TRAIT	YES - A COMPONENT OF THE TIC TRAIT
Is the TIC-CP2 phenotype a component of the cross-incompatibility barrier?	YES - A COMPONENT OF THE TCB TRAIT	YES - A COMPONENT OF THE TIC TRAIT
Is at least one modifier gene identified and described?	YES	NONE DESCRIBED
Is a gene that encodes for the silk effect function identified and described?	YES	NONE IDENTIFIED, DESCRIBED OR SUGGESTED
Are any linked molecular markers described?	YES	NONE IDENTIFIED, DESCRIBED

Additionally, in the previous Amendment, a 37 C.F.R. Section 1.132 Declaration of Dr. Jerry L. Kermicle (hereinafter referred to as the “Kermicle Declaration”) was submitted. As discussed in Paragraph 5 of the Kermicle Declaration, Kermicle et al. teach that the two (2) components of the TIC trait are (1) TIC-CP1; and (2) TIC-CP2. Additionally, Kermicle et al. hypothesized that the TIC trait encompassed another factor or factors which were unknown to the authors in 1990.

As the Kermicle Declaration discusses in Paragraph 6, after several years of further experimentation and breeding with plants containing the TIC trait, additional maize plants were developed that exhibited a cross-incompatible phenotype. These plants exhibited a phenotype different from the phenotype exhibited by the maize plants containing the TIC trait. This phenotype was referred to as the “teosinte crossing barrier” or TCB trait. Unlike plants containing the TIC trait that exhibited the TIC phenotype, plants exhibiting the TCB trait and the TCB phenotype do not contain TIC-CP1. As explained in the Kermicle Declaration, this finding was surprising in view of the work described in Kermicle et al. where TIC-CP1 was considered to be one of the two components of the cross-incompatibility barrier comprising the TIC trait (See Paragraph 7 of the Kermicle Declaration). In fact, Applicants submit that one of ordinary skill in the art reading Kermicle et al. (1990) would reasonably conclude that TIC-CP1 would be a necessary component of the TCB trait.

The Examiner states that page 17 of the specification, lines 6-7 states that the “TIC-CP1 gene(s) is associated with the pollen effect function of *Tcb*”. Applicants would like to respectfully point out that this sentence in the specification contains a typographical error. This sentence should recite that the “TIC-CP1 gene(s) is associated with the pollen effect function of *Ga1*”. Applicants direct the Examiner’s attention to Figure 4A, wherein TIC-CP1 is referred to and in parenthesis it says (*Ga1-m*).

As shown in the above Table A as well as Paragraph 8 of the Kermicle Declaration, in addition to discovering that TIC-CP1 was not a component of the TCB trait, the inventors further discovered that the TCB trait was encoded by a gene cluster comprising a *Tcb* locus and at least one modifier gene. The *Tcb* locus governs recognition between pollen and pistil. Kermicle et al. did not teach any modifier gene. Additionally, Kermicle et al. did not identify, teach the silk effect function of the TCB trait nor did it identify, disclose or suggest any molecular markers that might be useful for identifying the TIC trait. The present application

identifies and describes several molecular markers that allow one of ordinary skill in the art to identify plant material containing the gene cluster that encodes for the TCB trait using routine techniques known in the art. Therefore, as evidenced by the above-information, the plants of Kermicle et al. and the plants of the claimed present invention are not identical.

In the Office Action, the Examiner states that “page 17 of the specification indicates that a plant that contains the *Tcb* locus also contains the TIC-CP1 gene.” Applicants respectfully submit that this statement by the Examiner is incorrect. What page 17 states is that the inbred W22-TCB contains a gene cluster that encodes the TCB trait and in addition, TIC-CP1. W22-TCB can be used in crosses to develop plants that are cross-incompatible and that contain the gene cluster that encodes the TCB trait but that do not contain TIC-CP1. As explained above, Paragraph 8 of the Kermicle Declaration states that TIC-CP1 is not a component of the TCB trait.

Thereupon, based upon the arguments provided above, Kermicle et al. fail to disclose or each and every element of the claimed invention. Therefore, Applicants submit that this rejection should be withdrawn.

Claims 1-5, 9-17, 21-35, 39-50, 55-68 and 69-72 remain, and newly submitted claims 74-77 and 79-80 are rejected under 35 U.S.C. Section 103 as being obvious over Kermicle et al. (1990) taken with Nelson. The Examiner maintains that “Nelson teaches the general advantages of crossing maize plants containing cross-incompatibility factors, including those taught by Kermicle et al. (1990), for the controlled production of inbreds and hybrids, as discussed previously. Furthermore, many of the claims are not limited to any particular *Tcb* gene cluster or *Tcb* locus at any particular chromosomal location or derived from any particular parental plants.” Applicants respectfully traverse this rejection.

Kermicle et al. (1990) was discussed above. Nelson is a chapter from *The*

Maize Handbook. In this chapter, Nelson reviews various gametophyte factors in maize. The first Office Action referred to various paragraphs in Nelson. Specifically, the paragraph bridging pages 496-497, the bottom two paragraphs on page 499, the top paragraph on page 500, and the second full paragraph on page 501.

The paragraph bridging pages 496-497 discusses the crosses (specifically those involving crosses between Rice Popcorn and sweet corn (*sugary1*)) that lead to the identification of the fourth chromosome locus, *gametophyte factor1* (*ga1*). *Gametophyte factor1* is different from the TCB trait. The recessive allele, *ga1*, at the *gametophyte factor1* locus is typically found in dent corn. Specifically, *ga1* pollen is capable of fertilizing other dent corn that contains this locus. However, *Ga1-s/Ga1-s* popcorn is not fertilized by *ga1* pollen. However, *Ga1 ga1* heterozygotes are usually fertilized by *ga1 ga1* homozygotes.

The second to last paragraph on page 499 of Nelson discusses how the inability of *Ga1-s/Ga1-s* plants to set seed with *ga* pollen can be exploited to protect maize being grown for special uses from contamination by dent (*ga*) pollen during hybrid seed production and the production of the crop itself. The last paragraph on page 499 that is carried over on to page 500 discusses the work described by Nelson in *Genetics* 37:101-124 (1952). This paragraph discusses the experiments conducted by Nelson relating to cross-sterility among popcorns using a series of reciprocal crosses. Nelson employed 10 popcorn inbreds from a number of varieties and a dent inbred, *Hy*, that was known not to be able to effect fertilization on several popcorn inbreds. What is not reported here is that in this work Nelson found that the success of the cross depended on whether or not *Ga1-s* was present as homozygote or a heterozygote. Specifically, Nelson found that when *Ga1-s* was present as a homozygote, the cross failed; but if present as a heterozygote, that the success of the cross was variable (See Evans et al., *Theor. Appl. Genet.*, 103:259-265, 259 (2001)).

In the second full paragraph on page 501 Nelson discusses the work of Kermicle et al. (1990) reported in *Maydica*, 35:399-408 (1990). The work of Kermicle et al. (1990) has been discussed previously. In fact, Applicants submit that with respect to its teachings regarding the TIC phenotype, Nelson does not teach anything new that has not already been taught by Kermicle et al. (1990).

Neither Kermicle et al. (1990) nor Nelson disclose or suggest the plants of the claimed invention. As discussed previously, the plants described by Kermicle et al. are not identical to the plants of the claimed invention. There is nothing in Kermicle et al. (1990) or in Nelson, individually or collectively, that discloses or suggests plants having the phenotype of the plants of the present invention. In fact, Applicants submit that one of ordinary skill in the art reading Kermicle et al. (1990) would expect TIC-CP1 to be a component of the TCB trait that encodes the TCB phenotype. Moreover, there is absolutely nothing in Kermicle et al. that discloses or suggests at least one modifier gene, a gene that encodes for the silk effect function or any disclosure of molecular markers that allow one of ordinary skill in the art to identify plant material containing the gene cluster and at least one modifier gene that encode for the TCB trait using routine techniques known in the art. Therefore, Applicants submit that this rejection should be withdrawn.

Applicants submit that the claims are now in condition for allowance.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account number 23-0785.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this Amendment is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on December 1, 2004.


Aidah Abdallah